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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,350	12/07/2000	Allan Svendsen	5200.220-US	1715
25908	7590	01/26/2005	EXAMINER	
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/732,350

**Applicant(s)**

SVENDSEN ET AL.

**Examiner**

Kathleen M Kerr

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 64-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/032,315.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-Final rejection (mailed on April 8, 2004), Applicants filed response received on September 8, 2004 (non-compliant) and October 20, 2004. No amendments to the claims were made. Thus, Claims 64-105 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for U.S. non-Provisional Application Nos. 09/036,260 (USPN 6,184,015) filed on September 15, 1999 and 09/032,315 (USPN 5,985,818) filed on February 27, 1998 as well as the foreign application 0222/97 filed in Denmark on February 28, 1997.

### ***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

3. Previous rejection of Claims 64-105 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant's pointing to specific support for the alleged new matter.

### ***Maintained - Claim Rejections - 35 U.S.C. § 112***

4. Previous rejection of Claims 64-95 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that because the parent laccase must be SEQ ID NO:10, some structural limitations are imposed; this is not the case. In the instant claims, any number of mutations to SEQ ID NO:10 can be imposed on the parent laccase

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to form the claimed variant laccase. Thus, no specific structural features are imposed by the claim language. Applicant also argues that the specification describes many other positions of mutation in SEQ ID NO:10; while this may be the case, again, these are not structural limitations of the instant claims. Applicant argues that these represent species of the claimed genus; the Examiner agrees. SEQ ID NO:10 is a 573 amino acid protein, a laccase. Twenty-five positions are noted by Applicant in their remarks, and another 12 positions are in the claims. This equates to about 6% of the full-length protein wherein mutations are known to cause certain effects. However, the claims include mutation at any of the 573 positions so as to retain laccase activity. No description of how these 6% of the positions (structure) related to the function is disclosed. Thus, the positions noted by Applicant in the remarks and in the claims do not constitute a representative number of species of laccases having any structure.

Applicant also argues that this is common language found in other patents. USPNs 5,770,419, 5,972,670, 5,998,353, and 6,277,611 all limit the mutations to particular regions or specific sites as related to a particular sequence; this is distinct from the instant claims wherein any part of SEQ ID NO:10 can be mutated. The case is similar for claims in USPN 5,925,554, which also requires the laccase also be at least 80% identical to SEQ ID NO:1. The “comprising” transitional phrase is not convincing since the entire claim structure and language must be considered.

5. Previous rejection of Claims 64-105 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for variant laccases of specific structure, does not reasonably provide enablement for variant laccases having undefined or broadly defined structures is maintained. Applicant's arguments have been fully considered but

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are not deemed persuasive for the following reasons. Applicant argues that based on the numerous examples of laccase variants disclosed in the instant specification, one could make any laccase without undue experimentation. While the Examiner agrees that obtaining SEQ ID NO:10 and mutating it at the particular positions noted in Claim 64 is enabled (note: the instant rejection is a scope of enablement rejection), the instant claims are not so limited. Any and all structures that can be made to produce laccase activity, so long as the few particular point mutations are present, read on the pending claims. This is an enormous genus. As previously noted,

“The instant specification describes the three-dimensional structure of laccase from *Coprinus cinereus*. The specification describes other laccases related as *Coprinus*-like laccases by sequence and homology to the *C. cinereus* sequence, some sequences having as little as about 57% homology with the *C. cinereus* laccase (see pages 4-7). While the instant specification points to sequence locations for mutations that might affect (1) oxidation potential, (2) pH optimum, (3) mediator efficiency, and (4) O<sub>2</sub>/OH<sup>-</sup> pathway based on the disclosed 3D structure (see pages 8-12), the overall structural requirements for proteins having laccase activity are not described. The specification presents no guidance or working examples in the production of laccase variants having mutations other than those specifically denoted on pages 8-12 wherein said mutants would retain their activity, i.e., their laccase-character. The nature of the invention is that the product is a large, functional protein and with such a great deviation from a sequence known to possess laccase activity, the predictability of functionality becomes extremely low. Such enormous breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation.

In particular for Claims 96-105, the Examiner notes that the parent claims require mutations relative to SEQ ID NO:10 (*Myceliophthora thermophila* laccase) but the overall structure must be similar to SEQ ID NO:1 (*Coprinus cinereus* laccase), which natively is only 56.5% homologous to SEQ ID NO:10 (see page 4).”

Thus, the process of producing all proteins having laccase activity wherein the structure is only limited by particular point mutations listed in Claim 64 is a huge undertaking. Neither the art nor

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the specification teaches such experimentation. Despite the high level of skill in the art of enzymology, still engineering enzyme activities is unpredictable and is accomplished by either rational or random methods followed by screening (see Cherry *et al.* Current Opinion in Biotechnol. (2003) 14:438-443). Such techniques may allow one of skill in the art to find the claimed laccases, but the requirement is to make the claimed laccases (see 35 U.S.C. § 112, first paragraph).

***Maintained - Claim Rejections - 35 U.S.C. § 102***

6. Previous rejection of Claims 64 and 68 under 35 U.S.C. § 102(b) as being anticipated by Germann *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants again argue that the protein of Germann *et al.* is not a variant since it is a wild-type protein. In rebuttal, the Examiner notes that the wild-type sequence of Germann *et al.* is identical to the variant sequence in the claim. As previously noted, "Germann *et al.* teach the amino acid sequence of laccase from *Neurospora crassa*. Said sequence, when aligned to SEQ ID NO:10 (see previously attached alignment), has the A108V mutation. Thus, the *N. crassa* sequence can be considered a mutant of SEQ ID NO:10 with numerous mutations, particularly the claimed mutation - A108V." Whether the product of the claimed protein is obtained by mutation of SEQ ID NO:10 or from a wild-type source, the product is still the same and is within the scope of the claimed invention. The rejection is, thus, maintained. The instant claims are drawn to a product, which may be produced by a particular method (mutation) or not.

***Summary of Pending Issues***

7. The following is a summary of the issues pending in the instant application:
- a) Claims 64-95 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
  - b) Claims 64-105 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
  - c) Claims 64 and 68 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Germann *et al.*

***Allowable Subject Matter***

8. The Examiner notes that claims would be allowable when drawn to variants having the exact sequence of SEQ ID NO:10 with only particular mutations noted.

***Conclusion***

9. Claims 64-105 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,



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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

January 19, 2005